VEN-A-CARE
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A Home I.V. and Nutritional Service

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SENSITIVE- DO NOT DISCLOSE- INFORMATION CONTAINED HEREIN RELATED TO PENDING FEDERAL CASE UNDER COURT ORDERED SEAL

October 2, 1996

Dr. Bruce Vladeck
Administrator
Health Care Financing Administration
Department of Health and Human Services
200 Independence Blvd. S. W.
Hubert Humphrey Building Room 314G
Washington, D. C. 20201

RE: **EXCESSIVE REIMBURSEMENTS FOR CERTAIN PHARMACEUTICALS BY THE MEDICARE AND MEDICAID PROGRAMS.**

Dear Dr. Vladeck,

Ven-A-Care of the Florida Keys, Inc. "VAC" has attempted for more than seven years to assist the Health Care Financing Administration "HCFA" and the State Medicaid programs in limiting infusion and inhalation pharmaceutical reimbursements to the reasonable levels contemplated by the enabling legislation. VAC is particularly concerned now about the continuing practice of the Medicare and Medicaid programs of paying exorbitant reimbursement for infusion and inhalation drugs which results in more than one billion dollars per year of federal funds being wasted. VAC's efforts, to date, have not resulted in much needed changes. Accordingly, we are appealing to you directly to insure that the necessary resources are dedicated to terminating this unnecessary loss of program dollars as soon as possible.

Enclosed with this letter you will find two volumes of exhibits that substantiate and support the fact that the Medicare and Medicaid programs are continuing to make excessive reimbursements to providers for infusion and inhalation pharmaceuticals. These reimbursements are at many multiples over and above the amount that the programs ever intended to pay.

BACKGROUND

VAC specializes in the provision of drugs that are administered parenterally as well as respiratory solutions and their necessary supplies and equipment. VAC is a Florida Medicaid, Champus, and Medicare Part B "PEN" provider and services patients whose medical benefits are administered by virtually all of the major health insurance companies. VAC was formed in 1987 by five physicians, three pharmacists, and two nurses in Key West, Florida.

Infusion pharmaceuticals are primarily utilized by patients being treated for various forms of Cancer and HIV diseases. As I am sure you are well aware, both of these diseases are affecting a rapidly expanding population of people in the United States. This fact will only compound the future problem of finding adequate funding sources in order to provide these much needed benefits.

For approximately seven years, we have diligently worked in an attempt to inform responsible government officials, including HCFA and others, of the cause and effect that excessive reimbursements for infusion and inhalation drugs are having on our health care delivery system. As a result of these excessive payments, the Medicare and Medicaid programs are expending more than one billion dollars annually in additional costs. These excessive reimbursements also serve as a vehicle that drives overutilization and fuels illegal kickbacks. Much of the information which we have provided over past several years is now being reported by the media (Exhibit 1) and substantiated by various governmental reports, including but not limited to, the following Office of the Inspector General reports:

1.) Supplier's acquisition cost for albuterol sulfate
2.) Medicare payments for nebulizer drugs
3.) A comparison of albuterol sulfate prices
4.) Review of pharmacy acquisition cost for drugs reimbursed under the Medicaid prescription drug program of the California Department of Health Services
5.) OIG physician's cost for chemotherapy drugs
6.) Inappropriate payments for total parenteral nutrition (TPN)

Over a year ago, we traveled to the HCFA in Baltimore and met with various representatives of your agency and made a detailed presentation regarding these excessive reimbursements and their impact on the health care delivery system. Unfortunately, for the Medicare and Medicaid programs as well as the American public, to date, no meaningful action has been either proposed or implemented by your agency to deal with these issues. We find this fact not only disconcerting but potentially the source of a major embarrassment to both your Agency and to the Administration.

AWP FRAUD ON THE PROGRAMS

Currently, Medicare and most Medicaid programs' reimbursement methodologies for pharmaceuticals is based on a factor of a drug's Average Wholesale Price, "AWP". For Medicare, this methodology is the average of the generic form of the drugs AWP and for most state Medicaid programs the methodology is at a small percentage reduction, approximately 10% off of a drugs AWP. This methodology determination was intended to make the Medicare and Medicaid programs prudent purchasers of pharmaceuticals.

AWP has become the benchmark in the industry for establishing pharmaceutical reimbursement. Virtually every federally sponsored program, including Medicare, Medicaid, Champus, Federal Employees, and Railroad Workers as well as most private third-party programs is relying on AWP to base their reimbursement decisions (Exhibit 6,7,8,9, and 10). Unfortunately, the pharmaceutical manufacturers have circumvented the intent of the government's reimbursement methodology by falsely reporting inflated AWP pricing information enabling providers to reap windfall profits from the provision of infusion and respiratory drugs.

In 1995, the Medicare program had allowable charges of more than one billion dollars for approximately 50 infusion and inhalation drugs (Exhibit 2). Using these drugs as a basis for illustration, we compiled VAC's cost from a multitude of wholesale sources and compared them to Medicare's reimbursement (Composite exhibit 3). Based on these results, we found that Medicare's reimbursement was excessive and in many cases provided profit margins of more than 500% and, in some instances, more than 1000%. For some drugs, the 20% Medicare co-insurance payment is equal to or greater than the cost of the drug. Needless to say, the financial impact is being borne not only by the programs but by the beneficiaries and Medicare secondary payers who are responsible for the 20% co-payment.

To illustrate the magnitude of this problem, we recalculated the Medicare program's cost for these drugs using VAC's *best price* (Exhibit 4) and VAC's *worst price* (Exhibit 5). The *best* and *worst prices* do not represent "weekly specials" (Exhibit 15) which are widely available from wholesalers and can create additional savings on average of approximately 20%. It also does not take into account purchasing in bulk volume or multidose vials which also provide approximately 10- 20% savings or profit (Composite exhibit 3).

An example of a provider maximizing profits through purchases of drugs in bulk or multidose vials is the drug Ceftriaxone sodium, HCPCS J0696- 250mg.(Composite exhibit 3-3). VAC's best price for 250mg is $9.37. However, if VAC purchases a 2gm. vial that yields eight 250mg doses, the cost for each dose is reduced significantly to $6.88 per 250mg.(the cost of the 2gm. vial is $54.98). This represents an additional 14% savings or profit. Based on VAC's cost, the Medicare program alone can achieve annual savings of approximately $350 to $500 million dollars for the drugs listed in our exhibits. Similar savings can be achieved by the State Medicaid programs over and above the cost-containment mechanisms already in place, such as the rebate program.

Third-party payers are unable to accurately estimate costs for infusion and inhalation drugs because drug manufacturers falsely inflate their drugs pricing information, including but not limited to, AWP. The manufacturers are and have been reporting false and fraudulent drug pricing information, including a drug's AWP, direct price,"DP", and wholesaler acquisition cost, "WAC" (Composite exhibit 12). Drug manufacturers are in direct control of all pricing information provided to the marketplace, from the wholesale price to the amount of reimbursement (and thus the desired level of profits for their customers) by the Medicare and Medicaid programs. By falsely inflating drug pricing information, the drug manufacturers increase the profit margins enjoyed by their customers, thereby driving demand upward and increasing utilization. In some instances, the available profit margins arising from the manufacturers' false pricing information creates and incentive for the physician to utilize the manufacturer's drug rather than that of a competitor or prescribe alternative courses of treatment.

A number of years ago, the Florida Medicaid program changed its reimbursement methodology from AWP minus 10% plus a dispensing fee to WAC plus 7% plus a dispensing fee in an effort to further limit Medicaid pharmaceutical expenditures. The pharmaceutical manufacturers have thwarted Florida's attempt to control reimbursement for infusion and respiratory drugs by falsely reporting inflated WAC information. Additionally, Congress, has for a number of years been concerned about the spiraling costs of pharmaceuticals in the Medicare and Medicaid programs as evidenced by its enacting the Medicaid rebate program. For infusion and inhalation drugs, the drug manufacturers have caused this enactment to be a miserable failure in what can only be characterized as a farce. This outrage is easily demonstrated by the drug Leucovorin calcium manufactured by Elkins-Sinn. A 50mg. vial's NDC number is 00641-2369-41, its AWP is $56.25 and its DP is $45.00 as reported by the manufacturer. However, its true cost to providers is approximately $4.00. The Florida Medicaid program's reimbursement for this drug is approximately $46.00 (in addition applicable dispensing fee) which is more than twice Medicare's allowable for HCPCS J0460 (50mg. Leucovorin). Under the intent of the Medicaid rebate program, Florida should be receiving a rebate of approximately $4.60. When it comes to paying rebates to the State Medicaid programs, the drug manufacturers are truthfully reporting their required cost information and Florida receives a rebate of only $0.46!

Seizing the opportunity to exploit their control over drug prices, the drug manufacturers have in some instances, reported higher prices for generic products than the equivalent brand. In truth and in fact, the prices paid by the providers are much less. An example of this deceitful pricing practice is the drug Etoposide, HCPCS codes J9181 and J9182. This drug was a single source innovator drug produced under the brand name Vepesid by Bristol-Myers. Bristol-Myers reported an AWP of $136.49 for 100mg.(which was also false since

the true AWP was approximately $80.00). When Vepesid came off patent, the first generic was produced by Gensia. Gensia reported an AWP of $141.97 for their generic version of 100mg. Etoposide and thus caused the Medicare program to increase the allowable from $136.49 to $141.97! Simultaneously, the free market was working because the providers began to enjoy lower prices for purchasing Etoposide due to competition. These lower prices were dramatic. As of today, there are two additional manufacturers, Pharmacia and Chiron, who have priced their AWP for Etoposide 100mg. at $136.49 (same as Bristol-Myers) and $140.00 , respectively. The price for 100mg. of Etoposide has plummeted to $18.00. However, the reimbursement from Medicare, Medicaid and other payers continues to be based on the fraudulent AWP.

The drug manufacturers are further exploiting their ability to falsify pricing information by using their falsifications of AWP as a marketing tool. This is particularly true in cases where payers, such as State Medicaid programs calculate separate reimbursements for each manufacturer's drug based on the drug's NDC numbers. Our company has been solicited on numerous occasions by drug manufacturers who brag about their use of falsely inflated pricing information as a reason for purchasing their product over a competitor's with a lower AWP.

We understand that the HCFA may be examining a plan that would, for Medicare only, abandon the AWP reimbursement methodology. We perceive three major flaws with such an approach. First, this approach is based on the erroneous assumption that there is something wrong with the historical concept of AWP. The damage to the Medicare and Medicaid programs is being caused by false pricing information being submitted by the drug manufacturers rather than truthful representations of AWP. In other words, the problem can't be fixed unless it is accurately defined. Second, any plan must insure that there is truth and honesty in drug pricing information provided by the manufacturers and upon which reimbursement decisions are based. Ignoring the drug manufacturers' propensity to falsify pricing information in order to drive up reimbursement and utilization will doom any new methodology to failure. Third, the Medicaid programs must not be ignored. Drug manufacturers must be precluded from continuing to submit false pricing information to State Medicaid officials which is perpetuating the fleecing of the Medicaid programs

We would be happy meet with you and answer any questions or concerns you may have on these very important issues.

Sincerely,

Zachary T. Bentley

T. Mark Jones

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